



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

JUL 14 1999 8 '99 JUL 19 P3:18

James E. Carlson  
President  
Remedio All Natural  
5875 Pacific Street  
Suite D  
Rocklin, California 95677

Dear Mr. Carlson:

This is in response to your letter of May 26, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Remedio All Natural is making the following claims, among others, for the product **Smoker's Defense**:

- "...helps to nutritionally support and maintain those bodily functions weakened by the use of tobacco"
- "People who are still smoking and those who have recently quit or are trying to quit may use Smoker's Defense"
- "...may be used by second-hand smokers who are passively exposed to others smoking"
- "...works to cleanse and counteract the toxic effects of smoking"
- "It may be used with any cessation protocol"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The claims that you are making for this product suggest that it is intended to treat, prevent, cure, or mitigate disease, namely addiction to nicotine (i.e., smoking) and those diseases that may result from smoking. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET286

Page 2 - Mr. James E. Carlson

Please contact us if you require further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.  
Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, San Francisco District Office, Office of Compliance, HFR-PA140

cc:

HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO)  
HFS-456 (file, r/f)  
HFS-450 (r/f, file)  
HFD-310 (BWilliams)  
HFD-314 (Aronson)  
HFS-605 (Bowers)  
HFV-228 (Benz)  
GCF-1 (Dorsey, Barnett, Nickerson)  
r/d:HFS-456:RMoore:6/9/99  
reviewed:GCF-1:ABarnett:6/30/99  
f/t:HFS-456:rjm:7/14/99:docname:65437.adv:disc38

May 26, 1999

Office of Special Nutritionals  
(HFS-450)  
Center For Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street S.W.  
Washington, D.C. 20204



Dear Office of Special Nutritionists:

Notice pursuant to 403 ® (6).  
Remedio All Natural makes the following notification:

1. Name and Address of Distributor:

Remedio All Natural  
5875 Pacific Street, Suite D  
Rocklin, CA 95677

2. Text of Statement Being Made:

Formulated by Dr. Don Sanchez using herbs from the traditions of the Native American and Hispanic cultures, Smoker's Defense helps to nutritionally support and maintain those bodily functions weakened by the use of tobacco.

People who are still smoking and those who have recently quit or are trying to quit may use Smoker's Defense. In addition, Smoker's Defense may be used by second-hand smokers who are passively exposed to others smoking. The unique herbal combination works to cleanse and counteract the toxic effects of smoking. It may be used with any cessation protocol. People who smoke can also enhance their health by brushing their teeth, gums, tongue and roof of mouth with bicarbonate of soda after each use of tobacco.

Smoker's Defense is intended to be used in conjunction with Basic Defense, a multi-vitamin-mineral product from Remedio All Natural.

The Food and Drug Administration has not evaluated these statements. This product is not intended to diagnose, treat, cure or prevent any disease.

3. Name of Dietary Ingredient:

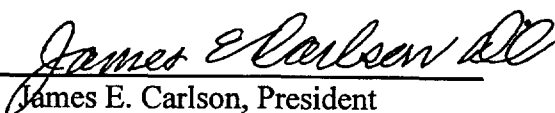
Smoker's Defense (proprietary herbal blend)

4. Name of Dietary Supplement:

Smoker's Defense

I, James E. Carlson, D.C., certify that the information contained in this notice is complete and accurate, and Remedio All Natural has substantiation that the statement is truthful and not misleading.

Dated: May 26, 1999

By:   
James E. Carlson, President  
Remedio All Natural